

KO42889

NOV 16 2004

Page 44



TELEPHONE: (727) 536-7831
FAX: (727) 539-6882 (Sales)
(727) 530-7310 (Purchasing)
(727) 532-3329 (Engineering)

SUMMARY 510 (k)

1. Submitter's Information:

Ametek, Inc.
8600 Somerset Drive
Largo, FL 33773
Contact – Philip LaChance
Tele # 727-536-7831 Ext 3384
Cell # 727-543-4894
Email Philip.lachance@ametek.com
Title – Engineering Manager

2. Classification Name: DC Powered Dynamometer

Common/Usual Name: Dynamometer

Proprietary Names:

- FCE-100 - 100 LBF (50 KGF, 500 N) Capacity
- FCE-200 - 200 LBF (100 KGF, 1000 N) Capacity
- FCE-500 - 500 LBF (250 KGF, 2500 N) Capacity
- MSC-100 - 100 LBF (50 KGF, 500 N) Capacity
- MSC-200 - 200 LBF (100 KGF, 1000 N) Capacity
- MSC-500 - 500 LBF (250 KGF, 2500 N) Capacity

3. Predictive Devices (manufactured by Ametek, Inc):

- CSD200 – 500 LBF Capacity
- CSD300 – 500 LBF Capacity
- CSD500 – 500 LBF Capacity

4. The Chatillon FCE and MSC series dynamometers are diagnostic devices used for quantitatively evaluating muscle strength. These instruments are powered by a rechargeable battery (4.8 VDC) which supplied a regulated 2.5 VDC excitation voltage to a strain gauge load cell. The analog output from the load cell (2 mV/V) is then converted to a digital signal that is directly proportional to the applied force. This digital signal is then sent to a microprocessor, which converts the signal to a force value that is stored in memory and/or displayed on the dynamometer graphical display. This design has been used for many years in industrial force measuring instruments and has been also used for physical therapy, occupational medicine and sports medicine. These medical dynamometers are a repackaged version of the industrial force measurement instruments and are designed with special medical attachments that are appropriate for performing manual muscle testing and ergonomic analysis.





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 16 2004

Mr. Phillip LaChance
Engineering Manager
Ametek
8600 Somerset Drive
Largo, Florida 33773

Re: K042889

Trade/Device Name: New Device – Chatillon FCE and MSC Series Dynamometer
Predictive Device – Chatillon CSD Series Dynamometer

Regulation Number: 21 CFR 888.1240

Regulation Name: AC-powered Dynamometer

Regulatory Class: II

Product Code: LBB

Dated: October 5, 2004

Received: October 19, 2004

Dear Mr. LaChance:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

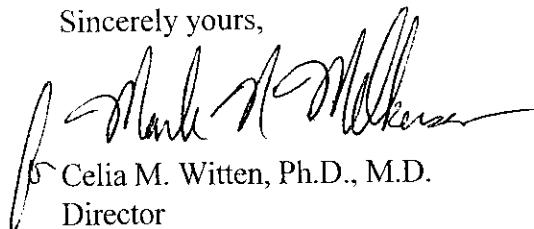
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Mr. Phillip LaChance

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K964685

Device Name: New Device – Chatillon FCE and MSC Series Dynamometer
Predictive Device – Chatillon CSD Series Dynamometer

Indications For Use:

The intended use of the Chatillon FCE and MSC series dynamometers is for performing manual muscle testing to measure muscle strength. The target population for this product is individuals recovering from physical injury or for sports medicine applications.

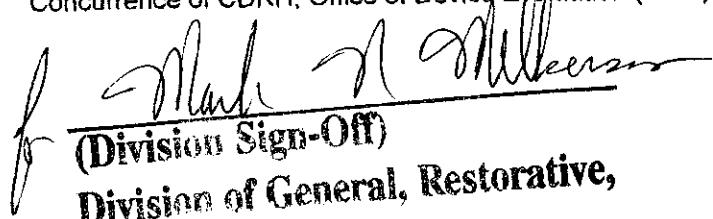
Prescription Use Yes
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number

K042889